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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,260	03/01/2001	Yasuaki Itoh	2543US0P	6283

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER	
MITRA, RITA	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,260	ITOH ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 6* is/are pending in the application.

4a) Of the above claim(s) 5 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicants' amendment in response to office action dated October 5, 2004 filed on December 29, 2004 is acknowledged. Claims 1, 3 and 6 have been amended. Claims 2, 4 and 7-10 have been canceled. Claim 5 has been withdrawn. Therefore, claims 1, 3 and 6 are currently pending and are under examination.

Response to Remarks and arguments

Rejections under 35 USC § 101 and 112, First Paragraph

The rejection of claim 2 under 35 USC § 101 and 112, First Paragraph is moot because claim 2 has been canceled.

Rejections under 35 USC § 112, Second Paragraph

The rejection of claims 1, 3 and 6 under 35 USC § 112, Second Paragraph being indefinite for reciting is withdrawn in view of the amendment to claims 1, 3 and 6.

The rejection of claim 2 under 35 USC § 112, second Paragraph is moot because claim 2 has been canceled.

Rejections under 35 USC § 102

The rejection of claims 3 and 6 under 35 USC § 102 is withdrawn in view of the amendment to claims 3 and 6. The rejection of claim 2 under 35 USC § 102 is moot because claim 2 has been canceled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 1, 3 and 6 stand rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The proteins of the invention are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed. The reasons are given in previous office actions dated March 25, 2004 (pages 2-6) and October 5, 2004 (pages 3-5).

In response Applicants traverse the rejection (page 4 of 'Amendment and Response'). The reason for traversal is on the ground of the present inventors have found cDNA having a novel base sequence at high levels in the lungs, trachea and stomach as illustrated in Example 2.

It is noted in Example 2 the Northern Blotting has been done using human multi-tissue Northern blots available commercially (Clontech) using a DNA probe prepared from the base sequence obtained from TGC-440 clone in the database (see Example 1). It has been stated in Example 2, the result revealed that the mRNA of this clone is expressed in limited tissues such as human lungs, trachea and stomach, and the mRNA was found to be an organ-specific expression product. However, the Example does not indicate that the mRNA used in the Northern blot was isolated from TGC-440 clone. It appears from the description that the experiment in example 2 is actually performed. The Example is not prophetic. Therefore, in absence of a figure depicting Northern Blot result or a complete description of the result, it cannot be concluded that the expression is tissue or organ specific. Moreover, it should be noted that the final result of the Northern Blot hybridization with a specific probe is related with the expression level of the mRNA. If the mRNA message is not abundant then the signal of hybridization may not be detected on the blot. Therefore, Applicants' arguments are not persuasive. It should also be noted that merely being a tissue specific marker is insufficient to meet utility requirements.

Additionally, Applicants comment on page 4 (Amendment and Response) that as proven by Example 7, a protein encoded by said cDNA is a humoral factor secreted extracellularly.

In response Applicants' attention is drawn to the page 2 of the specification, where it indicates, that the present inventors successfully found cDNA having a novel base sequence at high levels in the lungs, trachea, stomach etc., and found that 1) a protein encoded by said cDNA is a humoral factor actually secreted extracellularly, 2) a protein which has a signal sequence and comprises an amino acid sequence identical or substantially identical with the amino acid sequence represented by SEQ ID NO: 1, however the specification fails to provide any description of the biological activity of the protein in terms of signal transfer and self-protection as a humoral factor. The specification has not provided any sequence identity of the protein or percent similarity to the sequence of known member of humoral factor protein or to the sequence of a member that represents a class of humoral factor protein. Therefore, only on the basis of base sequence similarity it cannot be interpreted that the protein of invention would have similar activities of humoral factor protein. Since no activity of the protein has been provided in the specification, one skilled in the art would need to prepare, isolate and analyze the protein in order to determine its function and use, then only artisan can recognize the therapeutics indication for the protein so expressed.

As for the comment on having the claimed protein, as set forth in claim 1 as amended can be used as a pharmaceutical preparation for treating diseases such as trachea and bronchus-related diseases.....gastritis (see page 4, paragraph 2 of Amendment) have been reviewed. In response it should be noted that general uses of the protein set forth in the specification, include uses in the fundamental study such as molecular weight marker, tissue marker, chromosome mapping, identification of hereditary diseases, design of primer and probe etc. (page 4); uses for therapeutic or preventive purposes in fields such as inhibition of cancer metastasis etc.; in addition present invention is applicable for therapeutic and preventive purposes against diseases such as trachea- and bronchus related diseases etc. (page 4, 5). Examples of many diseases have been listed but the specification does not indicate explicitly the correlation of the role of any composition comprising the protein to a specific disease treatment or prevention. Also, high expression of the base sequence in lungs, trachea, stomach etc. does not indicate any link to

specific disease state and cannot be concluded that the protein would be useful in treatment or prevention of cancer metastasis etc. (see page 4). These general uses are not specific and substantial, as they do not require any one particular sequence.

In response to Applicants' comment on 'assertion of utility' it should be noted that in the instant case Applicants assert (see specification page 2 and supra) that the present inventors successfully found cDNA having a novel base sequence at high levels in the lungs, trachea, stomach etc., and found that 1) a protein encoded by said cDNA is a humoral factor actually secreted extracellularly, 2) a protein which has a signal sequence and comprises an amino acid sequence identical or substantially identical with the amino acid sequence represented by SEQ ID NO: 1. Applicants' assertion of utility is on the basis of structural similarity. It was stated in the previous office action (and also above) that specification has not provided any percentage similarity of claimed protein with any humoral factor protein or has described or demonstrated a correlation of this structural homology with any function that humoral factor protein may have. Therefore, this reason is sufficient for one skilled in the art to question the objective truth of the statement of utility.

As for the utility of the claimed protein as reagents for screening for a compound, which promotes or inhibits the function of the protein, it should be noted that when the function of the protein is not known how a person having skill in the art would be using the claimed protein as a reagent for screening a compound that would promote or inhibit the function of the protein.

Therefore, as per discussion above and in previous office actions, based on the specification it is unclear what activity the claimed protein possesses and therefore unclear how a person having skill in the art would be using the claimed protein. In summary, the protein claimed (claims 1, 3, 6) does not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 6 stand/are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The explanation given in 101 rejection (see previous office action and also supra) is also applicable to this rejection.

Claims 1, 3 and 6 stand/ are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3, directed to a method of producing the proteins of the sequence of SEQ ID NO: 1. As discussed above, the generic methods of production of the proteins by deriving from cells, by recombinant and by synthetic methods have been described in the specification (pages 12-33). However, when the function of the protein is not known, how a skilled artisan would know that the protein produced by these methods would have the same activity as to the activity of the protein of the present invention. The independent claim 1 as amended does not remove the deficiency; therefore the reasons for rejection given in the previous office action and also supra are applicable to this rejection.

Claim 6 is directed to a kit, for screening for a compound promoting or inhibiting the activity of the protein (claim 1) of the invention. The kit comprises the protein of the invention, however the specification fails to describe the activity of the protein. If the function of the product is not known one skilled artisan would not know how to use the product.

Therefore, as per discussion above and in the previous office action, the rejection of claims 1, 3 and 6 under 35 U.S.A. 112, first paragraph stands.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.
March 14, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER